

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jeffrey Hubbell, Jason Schense, Andreas Zisch and Heike Hall

Serial No.: Continuation of 10/024,918 Art Unit: Not Yet Assigned

Filed: August 27, 2003 Examiner: Not Yet Assigned

For: *ENZYME-MEDIATED MODIFICATION OF FIBRIN FOR TISSUE
ENGINEERING*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eleven (11) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 10/024,918, filed December 18, 2001, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

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INFORMATION DISCLOSURE STATEMENT

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<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



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Dated: August 27, 2003

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		<p>First Named Inventor</p>	<p>Jeffrey Hubbell</p>
		<p>Group Art Unit</p>	
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U.S. PATENT DOCUMENTS

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		ADAMS, et al., "Roles of ephrinB ligands and EphB receptors in cardiovascular development: demarcation of arterial/venous domains, vascular morphogenesis, and sprouting angiogenesis," <i>Genes & Development</i> 13:295-306 (1999).
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		EDELMAN, et al., "Controlled and modulated release of basic fibroblast growth factor," <i>Biomaterials</i> 12:619-626 (1991).	
		EDELMAN, et al., "Perivascular and intravenous administration of basic fibroblast growth factor: Vascular and solid organ deposition," <i>Proc. Natl. Acad. Sci USA</i> 90:1513-1517 (1993).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	Continuation of 10/024,918
		Filing Date	August 27, 2003
		First Named Inventor	Jeffrey Hubbell
		Group Art Unit	
Sheet	4	of	11
		Attorney Docket Number	CIT 2606 CIP CON

OTHER ART - NON PATENT LITERATURE DOCUMENTS		
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		EDGAR, et al., "The heparin-binding domain of laminin is responsible for its effects on neurite outgrowth and neuronal survival," <i>EMBO Journal</i> 3(7):1463-1468 (1984).
		ELICEIRI & CHERESH, "The role of ov integrins during angiogenesis: insights into potential mechanisms of action and clinical development," <i>Journal of Clinical Investigation</i> 103:1227-1230 (1999).
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		FERRARA & ALITALO, "Clinical applications of angiogenic growth factors and their inhibitors," <i>Nature Medicine</i> 5:1359-1364 (1999).
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		GÖTZ, et al., "Neurotrophin-6 is a new member of the nerve growth factor family," <i>Letter to Nature</i> 372:266-269(1994).

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		First Named Inventor	Jeffrey Hubbell
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		GRIESLER, et al., "Enhanced endothelial of expanded polytetrafluoroethylene grafts by fibroblast growth factor type 1 pretreatment," <i>Surgery</i> 112:244-255 (1992).
		HALL, "Molecular properties of fibrin-based matrices for promotion of angiogenesis in vitro," <i>Microvascular Research</i> 62:315-326 (2001).
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		HAMMOND, et al., "Management of coronary artery disease: Therapeutic options in patients with diabetes," <i>JACC</i> 36:355-65 (2000).
		HARADA, et al., "Basic Fibroblast Growth Factor Improves Myocardial Function in chronically Ischemic Porcine Hearts," <i>The American Society for Clinical Investigation, Inc.</i> 94:623-630 (1994).
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		HUBBELL, "Bioactive biomaterials," <i>Curr Opin Biotech</i> 10:123-129 (1999).	
		HUMPHRIES, "Integrin activation: the link between ligand binding and signal transduction," <i>Curr Opin Cell Biol</i> 8:632-640 (1996).	
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		KINOSAKI, et al., "Identification of heparin-binding stretches of a naturally occurring deleted variant of hepatocyte growth factor (dHGF)," <i>Biochemical Biophysica Acta</i> 1384:93-102(1998).	
		KLEINMAN, et al., "The Laminins: A Family of Basement Membrane Glycoproteins Important in Cell Differentiation and Tumor Metastases," <i>Vitamins and Hormones</i> 47:161-186 (1993).	

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		LEE, et al., "Analysis of affinity and structural selectivity in the binding of proteins to glycosaminoglycans: Development of a sensitive electrophoretic approach," <i>Biochemistry</i> 88:2768-2772 (1991).	
		LIN, et al., "Purification and Initial Characterization of Rat B49 Glial Cell Line-Derived Neurotrophic Factor," <i>Journal of Neurochemistry</i> 75:8-768 (1994).	
		LOPEZ, et al., "Basic Fibroblast Growth Factor in a Porcine Model of Chronic Myocardial Ischemia: A Comparison of Angiographic, Echocardiographic and Coronary Flow Parameters," <i>The Journal of Pharmacology and Experimental Therapeutics</i> 282(1):385-390 (1996).	
		LOPEZ, et al., "Short Communication, Local Perivascular Administration of Basic Fibroblast Growth Factor: Drug Delivery and Toxicological Evaluation," <i>Drug Metabolism and Disposition</i> 24(8):922-924 (1995).	
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		LYON, et al., "The Interaction of the Transforming Growth Factor- β s with Heparin/Heparan Sulfate is Isoform-specific," <i>The Journal of Biological Chemistry</i> 272(29):18000-18006 (1997).	
		MARTIN, "Laminin and Other Basement Membrane Components," <i>Annual Review of Cellular Biology</i> 3:57-85 (1987).	
		MASSIA, et al., "An RGD Spacing of 440 nm is Sufficient for Integrin α 5 β 3-mediated Fibroblast Spreading and 140 nm for Focal contact and Stress Fiber Formation," <i>The Journal of Cell Biology</i> 114(5):1089-110 (1991).	
		MAYSINGER, et al., "Microencapsulated nerve growth factor: effects on the forebrain neurons following devascularizing cortical lesions," <i>Neuroscience Letters</i> 140:71-74 (1992).	
		MCCAFFREY, et al., "Transforming Growth Factor- β 1 Is a Heparin-Binding Protein: Identification of Putative Heparin-Binding Regions and Isolation of Heparins with Varying Affinity for TGF- β 1," <i>Journal of Cellular Physiology</i> 152:430-440 (1992).	

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		MONTGOMERY, et al., "Human neural cell adhesion molecule L1 and Rat homologue NILE are ligands for integrin $\alpha_5\beta_3$," <i>J Cell Biol</i> 132:475-485 (1996).	
		NEHLS & HERRMANN, "The configuration of fibrin clots determine capillary morphogenesis and endothelial cell migration," <i>Microvascular Research</i> 51:347-364 (1996).	
		NETZEL-ARNETT, et al., "Sequence Specificities of Human Fibroblast and Neutropil Collagenases," <i>Journal of Biological Chemistry</i> 266(11):6747-6755 (1991).	
		NOLO, et al., "Developmentally Regulated Neurite Outgrowth Response from Dorsal root Ganglion Neurons to Heparin-binding Growth-associated Molecule (HB-GAM) and the expression of HB-GAM on the Targets of the Developing Dorsal Root Ganglion Neurites," <i>European Journal of Neuroscience</i> 8:1658-1665 (1996).	
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		REDDI, "Role of Morphogenetic Proteins in Skeletal Tissue Engineering and Regeneration," <i>Nature Biotechnology</i> 16:247-252 (1998).	
		ROGERS, et al., "Neuron-Specific Interactions with Two Neurite-Promoting Fragments of Fibronectin," <i>Journal of Neuroscience</i> 5(2):369-378 (1985).	
		ROSENGART, et al., "Angiogenesis Gene Therapy. Phase I assessment of direct intramyocardial administration of an adenovirus expressing phVEGF ₁₆₅ cDNA to individuals with clinically significant severe coronary artery disease," <i>Circulation</i> 100:468-474 (1999).	

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		RUOSLAHTI & ENGVALL, "Perspectives series: Cell adhesion in vascular biology," <i>J Clin Invest</i> 99:1149-1152 (1997).
		SAKATA & AOKI, et al., "Cross-linking of α_2 -plasmin inhibitor to fibrin by fibrin-stabilizing factor," <i>J Clin Invest</i> 65:290-297 (1980).
		SAKIYAMA, et al., "Incorporation of heparin-binding peptides into fibrin gels enhances neurite extension: an example of designer matrices in tissue engineering,"
		SAKIYAMA-ELBERT & HUBBELL, "Development of Fibrin Derivatives for Controlled Release of Heparin-Binding Growth Factors," <i>Journal of Controlled Release</i> 65:389-402 (2000).
		SCHENSE & HUBBELL, "Cross-Linking Exogenous Bifunctional Peptides into Fibrin Gels with Factor XIIIa," <i>Bioconjugate Chemistry</i> 10(1):75-81 (1999).
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		SHIN, et al., "Expression of EphrinB2 identifies a stable genetic difference between arterial and venous vascular smooth muscle as well as endothelial cells, and of adult neovascularization," <i>Developmental Biology</i> 230:139-150 (2001).
		SHIREMAN, et al., "Modulation of vascular cell growth by local cytokine delivery from fibrin glue suspensions," <i>J Vasc Surg</i> 19:852-62 (1999).

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		SHUMACHER, et al., "Induction of neoangiogenesis in ischemic myocardium by human growth factors," <i>Circulation</i> 97:645-650 (1998).
		SMITH, et al., "Rapid Identification of Highly Active and Selective Substrates for Stromelysin and Matrikine Using Bacteriophage Peptide Display Libraries," <i>Journal of Biological Chemistry</i> 270(12):6440-6449 (1995).
		SPILLMAN, et al., "Defining the Interleukin-8-Binding Domain of Heparan Sulfate," <i>Journal of Biological Chemistry</i> 273(25):15487-15493 (1998).
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number Continuation of 10/024,918	
		Filing Date First Named Inventor Group Art Unit Examiner Name	August 27, 2003 Jeffrey Hubbell
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		Attorney Docket Number	CIT 2606 CIP CON

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		THOMPSON, et al., "Site-directed neovessel formation in vivo," <i>Science</i> 241:1349-1352 (1988).	
		TYLER-CROSS, et al., "Heparin binding domain peptides of antithrombin III: Analysis by isothermal titration calorimetry and circular dichroism spectroscopy," <i>Protein Science</i> 3:620-627 (1994).	
		WANG, et al., "Molecular distinction and angiogenesis interaction between embryonic arteries and veins revealed by ephrin-B2 and its receptor Eph-B4," <i>Cell</i> 93:741-753 (1998).	
		WEATHERFORD, et al., "Vascular endothelial growth factor and heparin in a biologic glue promotes human aortic endothelial cell proliferation with aortic smooth muscle cell inhibition," <i>Surgery</i> 433-439 (1996).	
		YAMADA, "Adhesive Recognition Sequences," <i>The Journal of Biological Chemistry</i> 266(20):12809-12812 (1991).	
		YANISH-PERRON, et al., "Improved M13 phage cloning vectors and host strains: nucleotide sequences of the M13mp18 and pUC19 vectors," <i>Gene</i> 33:103-119 (1985).	
		ZUCKER, et al., "Platelet Factor 4: Production, Structure, and Physiologic and Immunologic Action," <i>Proceedings for the Society of Experimental Biology and Medicine</i> 198:693-702 (1991).	

Examiner's Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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